IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

(1) UNITED STATES OF AMERICA and (2) STATE OF OKLAHOMA, Plaintiffs, v. (1) COORDINATED CARE HEALTH SOLUTIONS, LLC d/b/a HUNTERCARE COORDINATED CARE HEALTH SOLUTIONS and (2) ERIC P. WALLIS, Ph.D., Defendants.	)	Case No. CIV-24-1185-JD

COMPLAINT OF THE UNITED STATES OF AMERICA
AND THE STATE OF OKLAHOMA

The United States of America and the State of Oklahoma jointly allege as follows:

I. INTRODUCTION

1. As more fully alleged below, this action arises from multiple schemes carried out by Defendant Coordinated Care Health Solutions, LLC d/b/a HunterCare Coordinated Care Health Solutions ("CCHS") and its laboratory director, Defendant Eric P. Wallis, Ph.D., ("Wallis"), to bill the United States and the State of Oklahoma for false and/or fraudulent claims for laboratory testing allegedly administered to beneficiaries of Medicare, Oklahoma Medicaid, TRICARE, CHAMPVA, and the Federal Employees Health Benefit Program (collectively "the Government Health Benefit Programs" or "GHBP").

2. Defendants disguised non-reimbursable urine drug tests as blood tests to by-pass Oklahoma Medicaid's prior authorization requirement for definitive urine drug testing services. CCHS submitted and Wallis caused the submission of claims for payment to Oklahoma Medicaid that misrepresented the services performed and included services that were not rendered. Defendants also submitted false and/or fraudulent claims for payment to Medicare, TRICARE, CHAMPVA, and the Federal Employees Health Benefit Program (collectively the "Federal Agency Government Health Benefit Programs" or "Federal Agency GHBP") for laboratory tests that were not rendered, not medically necessary, not used in the treatment of Federal Agency GHBP beneficiaries, performed and billed pursuant to impermissible blanket orders, and/or not ordered by a practitioner. These services did not comply with material requirements of GHBP laws, regulations, and program instructions, and were not reimbursable.

3. Defendants knew, acted in deliberate ignorance, or acted in reckless disregard of GHBP requirements, including that all billed services be performed as billed and medically reasonable and necessary for the treatment of an individual beneficiary. Defendants submitted false claims by making materially false express and implied certifications to get such claims paid. Defendants attempted to hide this systematic fraud by misrepresenting its services on claims for payment to evade Medicaid requirements, hiding its procedures and practices from rendering providers, and billing for tests without valid orders and when they were medically unnecessary.

4. As a result, Defendants generated a lucrative revenue stream and CCHS received millions in GHBP dollars to which it was not entitled.

5. The United States brings this action against Defendants pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), and federal common law to recover damages, as well as applicable civil penalties and treble damages.

6. The State of Oklahoma brings this action against Defendants pursuant to the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053.1 *et seq.* ("OFCA"), and state common law to recover damages, as well as applicable civil penalties and treble damages.

II. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732 and 28 U.S.C. §§ 1331 and 1345.

8. This Court has supplemental jurisdiction over all federal common law or equitable claims under 28 U.S.C. § 1367(a).

9. This Court also has supplemental jurisdiction over all OFCA and state common law claims pursuant to 28 U.S.C. § 1367(a) because those causes of action are so closely related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article III of the Constitution. This federal court jurisdiction over state law false claims is further authorized by the FCA itself, pursuant to 31 U.S.C. § 3732(b), as the federal and state claims arise from the same transactions and occurrences.

10. This Court has personal jurisdiction over Defendants and venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1391(c) because Defendants reside in this District, Defendants transact business in this District, and Defendants' conduct that gave rise to this case occurred in this District.

III. PARTIES

11. Plaintiff United States of America brings this action on behalf of the Department of Health and Human Services, the Department of Defense, the Department of Veterans Affairs, and the Office of Personnel Management.

12. Plaintiff State of Oklahoma brings this action on behalf of the Oklahoma Health Care Authority.

13. The Department of Health and Human Services ("HHS") is an agency and instrumentality of the United States, and the Centers for Medicare and Medicaid Services ("CMS") is the component agency of HHS that administers and supervises the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare"). *See also* 42 C.F.R. Ch. IV, Subchapter B.

14. The Department of Defense ("DoD") is an agency and instrumentality of the United States, and the Defense Health Agency ("DHA") is the component agency that administers and supervises the TRICARE Health Plan (formerly known as CHAMPUS) established and governed by 10 U.S.C. Chapter 55 and 32 C.F.R. Part 199 ("TRICARE").

15. The Department of Veterans Affairs ("VA") is an agency and instrumentality of the United States, and the Veterans Health Administration ("VHA") is the component agency that provides healthcare services and coverage benefits to veterans of the United States military and in certain instances, their spouse and dependents via the Civilian Health and Medical Programs of the VA ("CHAMPVA").

16. The Office of Personnel Management ("OPM") is an agency and instrumentality of the United States. OPM administers and oversees the Federal Employees Health Benefits Program ("FEHBP"), established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act, codified at 5 U.S.C. §§ 8901 *et seq.*, ("FEHBA"). *See also* 5 C.F.R. Part 890.

17. The Oklahoma Health Care Authority ("OHCA") is an agency and instrumentality of the State of Oklahoma. OHCA administers and determines financial eligibility for the Medicaid program in Oklahoma.

18. CCHS is a diagnostic laboratory and an Oklahoma professional corporation currently having its principal place of business at 10120 Broadway Ext., Suite 220, Oklahoma City, Oklahoma 73114. At all times relevant to this Complaint, CCHS's principal place of business has been in Oklahoma City, Oklahoma. CCHS purports to perform laboratory testing services ordered by third-party practitioners to monitor and treat their patients.

19. Wallis is a resident of Oklahoma City, Oklahoma and at all times relevant to this case was employed by CCHS as its laboratory director. At all times relevant to this

Complaint, Wallis was a management official, directed CCHS's laboratory operations, and supervised the laboratory employees, including the CCHS billing supervisor. Wallis directed and approved the fraudulent schemes implemented at CCHS.

IV. LAW

a. The Federal False Claims Act

20. The FCA provides, in pertinent part, that a person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains . . . .

31 U.S.C. § 3729(a)(1). For purposes of the FCA,

> (1) the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

b. The Oklahoma Medicaid False Claims Act

21. The OFCA provides, in pertinent part, that a person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the State of Oklahoma for a civil penalty consistent with the civil penalties provision of the Federal False Claims Act, 31 U.S.C. 3729(a), as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 101-410), and as further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Public Law 114-74), plus three times the amount of damages which the state sustains because of the act of that person.

63 O.S. § 5053.1(B). The definitions of "knowing" and "knowingly" under the OFCA are materially the same as the definitions of the terms under the FCA.

c. The Relevant Government Health Benefit Programs

i. <u>The Medicare Program</u>

22. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Medicare is a federal health insurance program that provides coverage for individuals based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. Medicare is funded by premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

23. Medicare consists of four distinct parts, only one of which is relevant

here. Defendants submitted claims under Medicare Part B, which covers certain medical services, such as clinical laboratory test services, furnished by physicians and other suppliers and providers. 42 U.S.C. § 1395k(a)(2)(B).

24. CMS administers the Medicare program. CMS contracts with private contractors, referred to as Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by healthcare providers. 42 U.S.C. § 1395u; 42 C.F.R. Part 421. At all times relevant to this Complaint, Novitas Solutions, Inc., ("Novitas") was the MAC for the UDT services billed to Medicare by Defendants.

25. To participate in the Medicare program as a new enrollee, providers must submit a Medicare Enrollment Application, CMS Form-855B. Enrolled providers must complete a new Form CMS-855B to change their enrollment information or to reactivate, revalidate, and/or terminate Medicare enrollment.

26. Medicare requires providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare laws, regulations, and program instructions. 42 C.F.R. § 424.516(a)(1).

27. To enroll as a Medicare provider, CCHS was required to sign an "Authorized Official Certification Statement for Clinics and Group Practices", which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." This certification statement is part of the Medicare Enrollment Application, CMS Form-855B.

28. An authorized official for CCHS signed the first Authorized Official

Certification Statement for Clinics and Group Practices on September 18, 2015. CCHS also submitted an executed "Delegated Official Certification Statement for Clinics and Group Practices" dated September 16, 2015. Authorized and delegated officials have since executed the same certification statements multiple times on behalf of CCHS. In each of these certification statements, CCHS agreed:

a. to abide by the applicable Medicare laws, regulations, and program instructions;

b. the Medicare laws, regulations, and program instructions are available through the Medicare contractor; and

c. payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with Medicare laws, regulations, and program instructions…and on the supplier's compliance with all applicable conditions of participation in Medicare.

29. In or around August 2021, CCHS submitted a CMS Form-855B to report a change in its Medicare enrollment information. The certification statement in Section 15 of the Form 855-B was signed by CCHS's Operations Manager and dated August 23, 2021. In this statement, CCHS again agreed:

a. to abide by the applicable Medicare laws, regulations, and program instructions;

b. the Medicare laws, regulations, and program instructions are available through the Medicare contractor; and

c. payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with Medicare laws, regulations, and program instructions…and on the supplier's compliance with all applicable conditions of participation in Medicare.

30. To obtain Medicare reimbursement for administered medical services, including urine drug testing ("UDT"), providers submit a claim form known as the CMS 1500 form or its electronic equivalent known as the 837P format.

31. To submit electronic claims via the 837P format, a provider must complete and submit to CMS an Electronic Data Interchange Enrollment Form ("EDI"). The EDI may be completed by the provider or an authorized individual who has the legal authority "to commit the provider to abide by the laws, regulations, and the program instructions of Medicare." On the EDI, the provider agrees to "submit claims that are accurate, complete, and truthful" and certifies that the use of the provider's NPI on a claim "constitutes the provider's legal electronic signature and an assurance that services were performed as billed." The provider's EDI certification then serves as the signature for every electronic claim submitted by the provider thereafter.

32. The first EDI relevant to the claims at issue in this case was sent to Novitas by CCHS by facsimile with the signature of CCHS's "Owner/President" and was dated July 30, 2018.

33. Among the information the provider includes on a CMS 1500 or the 837P electronic claim are Current Procedural Terminology Codes ("CPT codes"), CMS Healthcare Common Procedure Coding System ("HCPCS") codes, and/or modifiers to such codes. These codes are the providers' express identification of the services rendered and certification that such services are reimbursable.

34. Providing accurate CPT and HCPCS codes in claims is material to and a condition of payment for GHBP. *See*, *e.g.*, Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

35. As a Medicare enrolled provider, CCHS must:

a. Obtain the required certification and, recertification statements;

b. Keep them on file for verification by the intermediary, if necessary; and

c. Certify, on the appropriate billing form, that the statements have been obtained and are on file.

42 C.F.R. §§ 424.10, 424.11(a).

36. Additionally, when submitting the CMS 1500 to Medicare for payment, providers such as CCHS must certify:

a. the claim is truthful, accurate, and complete;

b. the provider familiarized themselves with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor;

c. the claim complies with all applicable Medicare laws, regulations, and program instructions for payment; and

d. the services on the claim form were medically necessary.

37. The provider also must include on the CMS 1500 form or 837P format a National Provider Identifier ("NPI"), which is a unique 10-digit identification number corresponding to a specific healthcare provider. Claims for diagnostic laboratory services must include the NPI for the "billing provider or group", "rendering provider," and "ordering/referring provider." Medicare Claims Processing Manual, Ch. 26, § 10.4.

38. The UDT claims submitted to CMS at issue in this action identified CCHS (NPI 1871960195) as the billing provider and the rendering provider. Wallis caused the submission of the claims for payment relevant to this case.

39. The UDT claims at issue here were submitted for payment by CCHS to Novitas, the MAC responsible for processing such claims in the State of Oklahoma. Wallis caused the submission of the claims for payment relevant to this case.

40. Generally, after a provider submits the CMS-1500 or 837P claim to Novitas, the claim is paid directly to the provider without any review of supporting documents, including medical records.

41. During the time period relevant to this Complaint, CCHS submitted and Wallis caused the submission of UDT claims for payment to Medicare via Novitas.

ii. SoonerCare / The Oklahoma Medicaid Program

42. SoonerCare, the Oklahoma Medicaid program ("Medicaid"), is a joint federal-state program that provides health care benefits for certain groups, including the poor and disabled. 42 U.S.C. §§ 1396 *et seq*. The Medicaid program was created in 1965 in Title XIX of the Social Security Act.

43. Under the Social Security Act, Medicaid funding is shared between the state and federal governments. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d-(b). Thus, each claim submitted for payment to the Oklahoma Medicaid program is paid with state and federal

dollars according to the FMAP.

44. Each state Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a.

45. Oklahoma, through statutes, administrative rules, and provider agreements, requires Medicaid providers to certify compliance with federal and state law.

46. A provider's participation in the Oklahoma Medicaid program is voluntary.

47. To be eligible for payment by the Oklahoma Medicaid program, providers must have an approved Provider Agreement on file with the OHCA. Okla. Admin. Code § 317:30-3-2. Through this Provider Agreement, "the provider certifies all information submitted on claims is accurate and complete, assures that the State Agency's requirements are met and assures compliance with all applicable Federal and State regulations." *Id.*

48. An authorized official for CCHS submitted a Provider Application on January 19, 2016. CCHS entered into a Provider Agreement with Medicaid on January 21, 2016.

49. Similar to Medicare billing requirements, approved providers submit claims to the OHCA for Medicaid reimbursement for administered medical services, including UDT, through submission of an 837P or CMS 1500 claim in the Medicaid provider portal.

50. Claims accepted into the Medicaid provider portal are issued a unique tracking number known as the Internal Control Number ("ICN") or the claim ID number.

51. Claims submitted to Medicaid must identify the provider and describe the services rendered by reference to the CPT or HCPCS code applicable to the specific service provided. Providers are reimbursed based on a fee schedule of allowable rates that correspond to the applicable CPT or HCPCS code.

52. Providers certify with each claim for payment that the services or products for which payment is billed by or on behalf of the provider were medically necessary as defined by O.A.C. § 317:30-3-1(f) and were rendered by the provider. Providing accurate CPT and HCPCS codes in claims is material to and a condition of payment by the OHCA.

53. If a provider contracts with a third party to provide billing services or submit claims on behalf of the provider, the provider is "responsible for the accuracy and integrity of all claims submitted on behalf of [the] Provider by the billing service." *See* Medicaid's General Provider Agreement.

54. During the time period relevant to this Complaint, CCHS submitted and Wallis caused the submission of claims for payment to Medicaid.

iii. The TRICARE Program

55. TRICARE is a government-funded healthcare program for uniformed services members, retirees, and their families around the world. TRICARE is managed by DHA in two state-side regions. Defendants' conduct and submission of false claims all

occurred within TRICARE's East Region wherein Humana Military is the assigned regional contractor assisting DHA. Wisconsin Physicians Service ("WPS") is Humana Military's claims processing contractor in the TRICARE East Region.

56. DHA provides Humana Military with guidance (as issued by DoD) for administering TRICARE-related laws. DoD issues this direction through modifications to the Code of Federal Regulations and TRICARE manuals.

57. TRICARE presumes "the provider of the services is responsible for the actions of all individuals who file a claim on behalf of the provider." 32 C.F.R. § 199.2.

58. To be eligible for reimbursement by TRICARE, medical services must be medically necessary and required in the diagnosis and treatment of illness or injury. *See, e.g.*, 32 C.F.R. §§ 199.2, 199.4(a)(1)(i), & 199.9(b)(3). UDT that is routine, not based on patient-specific medical decision-making, and/or does not impact the medical management of the patient is not medically necessary and therefore not reimbursable under TRICARE.

59. TRICARE defines "abuse" as practices that are "inconsistent with accepted sound fiscal, business, or professional practice which result in a [TRICARE] claim, unnecessary cost, or [TRICARE] payment for services or supplies that are…[n]ot within the concepts of medically necessary and appropriate care." 32 C.F.R. § 199.2. Abuse is "a sufficient basis for denying all or any part" of a TRICARE health claim. One specific example of "abuse" is "[a] pattern of claims for services which are not medically necessary or, if medically necessary, not to the extent rendered. For example, a battery of

diagnostic tests are given when, based on the diagnosis, fewer tests were needed." 32 C.F.R. § 199.9(b)(3).

60. TRICARE also considers "flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician's orders" to be fraud. 32 C.F.R. § 199.9(c)(5).

61. For beneficiaries eligible for both Medicare and TRICARE, Medicare is the primary payer and TRICARE coverage is secondary. When such beneficiaries receive medical care, "the first determination will be whether payment may be made under Medicare." 32 C.F.R. § 199.8(d)(1)(iii). That determination is made according to Medicare "exclusions, conditions, and limitations." *Id.*

62. Depending on their network status, non-institutional providers may submit paper claims to TRICARE using the CMS 1500 claim form (discussed above). When submitting an electronic claim form to TRICARE, the provider makes the same certifications as on the CMS 1500 claim form.

63. During the time period relevant to this Complaint, CCHS submitted and Wallis caused the submission of UDT claims for payment to TRICARE via WPS.

iv. The CHAMPVA Program

64. The VA offers this healthcare benefits plan that cost shares for Veterans and their beneficiaries covering healthcare services and supplies. Honorably discharged Veterans who are determined permanently and totally disabled as well as meeting other eligibility requirements are covered under this program, along with their spouses,

surviving spouses, dependent children, and family caregivers. 38 U.S.C. §§ 1710, *et seq.*

65. Current and surviving spouses or children of a Veteran with disabilities or a service member who died in the line of duty who otherwise do not qualify for TRICARE are potentially eligible for health insurance through CHAMPVA. 38 U.S.C. § 1781(a).

66. CHAMPVA limits coverage to allowable expenses only for "medical services and supplies that are medically necessary and appropriate for the treatment of a condition and that are not specifically excluded from program coverage." 38 C.F.R. § 17.272(a).

67. CHAMPVA is generally the secondary payer to all other government health care payer programs. CHAMPVA assumes primary payor status when the beneficiary has an entitlement to state Medicaid programs or State Victims of Crime Compensation Programs. 38 C.F.R. § 17.272(a)(3)(i-ii).

68. A provider who submits claims to CHAMPVA for reimbursement may submit them electronically or on a nationally recognized standardized paper (such as CMS-1500 or UB-04). Such claims must be submitted no later than one year after the date of service; or in the case of inpatient care, one year after the date of discharge; in the cases of retroactive approval for services/supplies and retroactive approval of beneficiary eligibility, 180 days following the notification of authorization. *See* 38 C.F.R. § 17.275.

v. <u>The FEHBP</u>

69. The FEHBP is a federally funded insurance program for federal

employees, retirees, and their dependents under the age of 26. Under the FEHBP, Federal agencies pay a portion of the insurance premiums for covered individuals.

70. OPM administers and oversees the FEHBP. Contributions to the FEHBP are maintained by the United States Treasury in the Employees Health Benefits Fund ("Fund"), which OPM also administers. 5 U.S.C. § 8909.

71. Federal agencies and their employees pay into the Fund through health insurance premiums. 5 U.S.C. § 8906. Federal employees' portions of the contribution are withheld from each paycheck, then forwarded to the Fund by the employing agency, along with the agency's share of the premium. Proceeds from the Fund are used to pay carriers for covered claims paid on behalf of FEHBP members. 5 U.S.C. §§ 8906, 8909.

72. FEHBA authorizes OPM to contract with private insurance carriers to offer healthcare benefits to federal employees. OPM enters into contracts with private insurance carriers to administer healthcare benefits, including the processing and payment of healthcare claims on behalf of FEHBP members. Proceeds from the Fund are used to reimburse carriers for covered claims paid on behalf of FEHBP members. 5 U.S.C. § 8902, § 8909(a).

73. The FEHBP plan at issue in this case is offered by BlueCross BlueShield ("BCBS").

74. In the FEHBP, the contracted carrier resolves claims filed under the carriers' FEHBP plan. All FEHBP health benefit claims must be submitted initially to the carrier for processing and payment. 5 C.F.R. § 890.105.

75. As with Medicare and TRICARE, the FEHBP plans cover only those medical services that are reasonable and necessary to prevent, diagnose, or treat an illness, disease, injury, or condition of the covered beneficiary. *See* 5 U.S.C. §§ 8902a(c)(4)-(5), 8902a(d).

76. For example, Section 5(a) of the FEHBP 2016 BCBS Service Benefit Plan for Oklahoma states all medical benefits "are subject to the definitions, limitations, and exclusions in this brochure and are payable only when we determine they are medically necessary."

77. In October 2016, the BCBS Federal Employee Program plans adopted FEP 2.04.98, Drug Testing in Pain Management and Substance Use Disorder Treatment. That policy outlines when certain types of UDT are considered medically necessary. For presumptive UDT, the requirements include "[t]here is a plan in place regarding how to use test findings clinically" and "[d]rug testing is ordered by a clinician during an office visit."

78. Conversely, FEP 2.04.98 states instances when UDT is not medically necessary include, but are not limited to, routine presumptive or definitive UDT drug testing and standing orders (*e.g.*, testing at every visit, without consideration for specific patient risk factors or without consideration for whether definitive testing is required for clinical decision making).

79. During the time period relevant to this Complaint, CCHS submitted and Wallis caused the submission of UDT claims for payment to the FEHBP via the OPM-

contracted health insurance plan offered by BCBS.

vi. The Government Health Benefit Programs Rely on Providers to be Truthful, Accurate, and Complete

80. Because it is not feasible for GHBP personnel to review every patient's medical record for the millions of claims for payment they receive from providers, the programs rely on providers to comply with program requirements and submit truthful, accurate, and complete certifications and claims.

81. Generally, after a provider submits the claim to GHBP, the claim is paid without any review of supporting documents, including medical records.

V. BACKGROUND

a. Types of Urine Drug Testing

82. Drug testing is used to determine the presence or absence of drugs or metabolites in a patient's system. Different testing methodologies have different capabilities and limitations.

83. Urine is a preferred medium for drug testing and is the medium for testing used by Defendants. Two types of UDT are relevant in this case.

84. Presumptive (or qualitative) drug testing typically expresses results as a negative or positive and is used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample. Presumptive UDT methods range from point-of-care dipstick tests to tests performed by instrumented chemistry analyzers and mass spectrometry, with reimbursement rates typically increasing with the complexity of the test.

85. Definitive (or quantitative) drug tests report the results in concentrations and are medically necessary to identify specific medications, illicit substances, and metabolites. Definitive UDT is typically reimbursed at higher rates than presumptive testing.

86. Presumptive UDT performed via an immunoassay is a biochemical test that measures the presence above a cutoff level of a substance (drug) with the use of an antibody. Immunoassay results primarily detect drug classes and a few specific drugs. In some configurations, immunoassay testing can provide immediate results for the immediate management of the patient.

87. In general, immunoassay presumptive UDT is less precise and reliable than definitive UDT. For example, such testing may not distinguish between different types of opiates, may not detect all drugs or drug classes, and/or may require a concentration level "cut off" that is too high to detect the presence of a certain drug.

88. Because of the specific limitations of presumptive immunoassays performed on a chemistry analyzer, subsequent targeted definitive testing may, in some situations, be reasonable and necessary to ensure the ordering practitioner has complete and accurate information to manage the patient's care. The medical necessity of definitive UDT depends on the unique presentation and condition of each patient, each patient's drug abuse history, and/or whether the results of a preceding presumptive test, if rendered, are expected or unexpected.

89. For example, if the presumptive test provides the clinician with sufficient

information for the treatment and diagnosis of a patient, a definitive test is not reasonable and necessary and not covered by GHBP.

90. For a presumptive test to be medically reasonable and necessary, it should be performed and resulted first, and used in the treatment and diagnosis of the patient.

91. The technological limitations on immunoassay UDT, however, do not apply to UDT performed using High Performance Liquid Chromatography coupled with Mass Spectrometry ("LC-MS").

92. LC-MS is a complex technology that uses the separation capabilities of liquid chromatography with the analytical capabilities of mass spectrometry. LC-MS technology allows providers to test urine specimens for numerous drugs and metabolites during a single run of an aliquot of a urine sample through the LC-MS machine.

93. Unlike point-of-care UDT, LC-MS UDT results are not available for the immediate management of the patient. In some situations, LC-MS UDT results are not available until several days later.

94. When a definitive test is performed on an LC-MS device, there is no medical purpose or reason for the LC-MS simultaneously to report "presumptive results" because definitive results contain the same information that a presumptive test provides, and more.

95. Often, as was the case here, an LC-MS runs the same set of tests on all samples for the technical convenience and cost-effectiveness of the laboratory—

irrespective of whether or not all of those tests are medically reasonable and necessary. The laboratory, however, may only bill GHBP for those tests that are medically reasonable and necessary to treat the beneficiary.

b. Requirements for Payment for Laboratory Services

96. Section 1862 of the Social Security Act, codified at 42 U.S.C. § 1395y(a)(1)(A), provides that under Medicare, "no payment may be made under part A or part B for any expenses incurred for items or services… [that] are not reasonable and necessary for the … prevention of illness."

97. When a provider submits a claim for payment to Medicare, they certify that the services both were provided as billed and are medically reasonable and necessary.

98. Similarly, under 42 C.F.R. § 411.15(k)(1) of the Medicare program regulations, any services that are not "reasonable and necessary…[f]or the diagnosis or treatment of illness or injury" are excluded from coverage.

99. To determine whether services are reasonable and necessary such that reimbursement is appropriate, Medicare requires complete documentation of services rendered to beneficiaries. *See* 42 U.S.C. §§ 1395l(e), 1395u(c)(2)(B)(i). A provider's claim for a diagnostic test, such as a urine drug test, is not medically reasonable and necessary if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. *See* 42 C.F.R. § 410.32(d)(3).

100. To be a reimbursable service under Medicare, all diagnostic testing "must be ordered by the physician who is treating the beneficiary, that is, the physician who

furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a); Medicare Benefit Policy Manual, Ch. 15, § 80.1. Medicare will not reimburse a provider for services that do not meet these requirements.

101. To be a "covered service" and eligible for payment by Medicare, UDT claims also must comply with Novitas' Local Coverage Determination L35006, *Controlled Substance Monitoring and Drugs of Abuse Testing* ("LCD"). This LCD covers services performed on or after October 1, 2015.

102. A blanket order is a "test request that is not for a specific patient" but instead is identical "for all patients in a clinicians' practice without individualized decision making at every visit." LCD at p.5. Under LCD 35006, UDT performed pursuant to a blanket order is not eligible for reimbursement. LCD at p.11.

103. Similarly, "the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice." LCD at p.10. UDT orders must be "individualized based on clinical history and risk assessment, and must be documented in the medical record." *Id.*

104. "Medical record documentation (*e.g.*, history and physical, progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a qualitative drug test. All tests must be ordered in writing by

the treating provider and all drugs/drug classes to be tested must be indicated in the order." LCD at p.5.

105. The Medicare-accepted presumptive UDT CPT codes for the time period relevant to this Complaint are 80305-80307.

106. At all times relevant to this Complaint, Defendants billed for presumptive UDT services using CPT 80307.

107. At all times relevant to this Complaint, Medicare required labs to use the following HCPCS codes (hereinafter "the G Codes") on claims for payment for definitive UDT:

G0480	Drug test(s), definitive … qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	Drug test(s), definitive … qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive … qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
G0483	Drug test(s), definitive … qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed

108. The more drug classes associated with the code, the larger the reimbursement rate. For example, services billed using HCPCS G0483 are reimbursed at a higher rate than services billed using HCPCS G0482.

109. Defendants had access to the LCD and applicable Medicare laws, regulations, and program instructions at all times relevant to this Complaint.

110. The other Federal Agency GHBP use rules similar to the Medicare laws, regulations, and requirements to determine if services are covered and reimbursable. Defendant had access to the laws, regulations, requirements, and program instructions of the other Federal Agency GHBP at all times relevant to this Complaint.

c. Medicaid's Additional Requirements for Payment for Laboratory Services

111. In addition to the Medicare requirements, Medicaid reimbursement for drug testing is subject to the additional rules and guidelines promulgated by the OHCA.

112. To be eligible for reimbursement by Medicaid, "[d]rug testing must be ordered by the physician or non-physician provider and must be individualized to the member and the member's medical history and/or assessment indicators as evidenced in the medical documentation." Okla. Admin. Code § 317:30-5-101(c).

113. Drug testing must "be medically indicated as evidenced by member specific indications in the medical record," and "[d]rugs or drug classes being tested should reflect only those likely to be present." Okla. Admin. Code §§ 317:30-5-101(c)(1), 317:30-5-101(c)(1)(B).

114. "Non-specific, blanket panel or standing orders for drug testing, routine testing of therapeutic drug levels, or drug panels which have no impact to the member's plan of care" are considered "not medically necessary and therefore not covered by the OHCA." Okla. Admin. Code §§ 317:30-5-101(d)(5).

115. OHCA also requires providers to obtain prior authorization from the Medical Authorization Unit for any definitive UDT claims submitted to OHCA for

payment.

116. In a provider letter dated January 5, 2016, OHCA advised providers of this new requirement, which took effect on March 1, 2016. OHCA 2016-01, Provider Letter re: Controlled Substance Monitoring and Drugs of Abuse Testing. This requirement was in place at all times relevant to this case.

117. To obtain prior authorization for definitive UDT, providers must demonstrate medically necessity, specifically set forth the clinician's rationale for the definitive drug testing, and the tests ordered must be documented in the patient's medical record. OHCA also requires:

> In all cases, drugs or drug classes for which definitive testing is performed should reflect only those likely to be present, based on the patient's medical history, current clinical presentation and illicit drugs that are in common use. In other words, it is NOT medically necessary or reasonable to routinely test for substances (licit or illicit), which are not used in the patient treatment population or, in the instance of illicit drugs, in the community at large. The ordering/referring provider must issue a written order for all drugs to be tested individualized to the patient.

and

> **Routine definitive testing or non-specific panel testing for all of the drugs/drug classes is excluded from coverage as not medically indicated. Automatic definitive testing for any drug is not reasonable and necessary without patient specific indications.** The test must be utilized only if it is going to affect patient care. If a previous presumptive drug test is negative, no further testing is necessary unless the clinician provides documentation of aberrant behavior to support the medical necessity of performing subsequent definitive testing.

OHCA Guideline, Controlled Substance Monitoring and Drugs of Abuse Testing (Jan. 1, 2017) (emphasis added). *See also* OHCA 2016-26, Provider Letter re: Prior Authorization Process for Definitive Urine Drug Testing (Aug. 31, 2016).

118. As a follow-up to Provider Letter OHCA 2016-01, OHCA issued a global message on January 11, 2016, stating:

> OHCA would not expect to see non-specific pathology/laboratory CPT codes billed in addition to the HCPCS codes for presumptive or definitive drug testing. These CPT codes include, but are not limited to: 80299, **82542**, 83516, 83518, 83519, 83520, **83789**, 84311 and 84999.
>
> If any of these CPT codes are billed as part of a service that is separate from presumptive or definitive drug testing, then documentation in the record should reflect the indication for ordering these tests. If these codes are paid along with the HCPCS codes noted above for drug testing alone, this is considered unbundling and is subject to recoupment.

Global Message, Follow-up to Provider Letter 2016-01 (Jan. 11, 2016) (emphasis added).

119. In the January 11, 2016 global message, OHCA specifically stated that "HCPCS codes G0480 through G0483 are the **only** codes a provider should submit for reimbursement when performing definitive drug testing." *Id.* (emphasis added).

VI. DEFENDANTS' FRAUDULENT SCHEMES

a. CCHS's Urine Drug Testing Operations

120. CCHS is a diagnostic laboratory performing toxicology, hematology, urology, and compliance testing. At all times relevant to the Complaint, CCHS maintained a toxicology department that was separate from the hematology department.

121. CCHS's toxicology department primarily processed urine samples and had responsibility for all tests relating to drug testing.

122. CCHS's hematology department primarily processed blood samples and, at some point, also conducted respiratory-related tests.

123. At all times relevant to this Complaint, Wallis was the lab director for and supervised and directed both departments.

124. CCHS initially used an enzyme immunoassay analyzer called the "Carolina" to perform presumptive UDT. Definitive UDT was performed on an LC-MS machine.

125. By late 2019, CCHS performed all UDT tests—presumptive and definitive—using an LC-MS machine.

126. CCHS moved the presumptive UDT to the LC-MS to save costs associated with operating the Carolina and to eliminate false positives.

127. After CCHS moved its presumptive UDT to the LC-MS, an aliquot of a urine sample was run through the LC-MS machine only once. CCHS used its laboratory information system software to split the resulting information into a "presumptive result" section and a definitive result section to give the appearance that two distinct services were rendered in each instance.

128. Defendants limited the information in the "presumptive results" section by arbitrarily excluding certain substances, directing that such results be reported at the drug class level, and setting less precise detection cut off limits, despite the LC-MS machine's technological capabilities.

129. For example, at Wallis's direction, CCHS's LC-MS device and/or the associated laboratory information system was programmed not to provide presumptive

UDT results for synthetic opioids, such as fentanyl, despite the LC-MS machine having that capability.

130. As another example, the cut off for detecting amphetamines in the presumptive result section was set at 1000 ng/mL, but the cut off used in the definitive result section was 200 ng/mL and 100 ng/mL for amphetamine and methamphetamine, respectively. Because these results were provided to the ordering practitioner at the same time and because it is less precise, the amphetamine presumptive result does not inform or impact patient management and treatment.

131. Wallis directed what UDT would be offered and performed by CCHS and decided what HCPCS and/or CPT codes to bill for each test or panel of tests.

132. CCHS's UDT test result forms state "[t]hese confirmatory tests were developed and the performance characteristics determined by CCHS Laboratories." The forms also identify Wallis as the lab director.

133. In both configurations, the results of the presumptive and definitive UDT were combined into a single report via CCHS's laboratory information system. The presumptive UDT results were provided to the ordering practitioner at the same time and in the same report with the definitive UDT test results.

134. Indeed, even when both presumptive UDT and definitive UDT were ordered, the presumptive results could not be viewed outside CCHS's laboratory information system until the definitive test was complete.

135. CCHS used different requisition forms for its toxicology and hematology departments. Wallis input the data for and had final approval over both forms.

136. CCHS's hematology requisition forms offered services such as complete metabolic panels, infectious disease testing, cardiac testing, and therapeutic drug monitoring ("TDM") tests.

137. CCHS directed ordering practitioners to fill out a "Physician Custom Profile" form, which was created by Wallis.

138. These generic forms include the ordering practitioner's name, office information, and signature and often have every urine drug test offered by CCHS selected to be part of the physician's "custom" profile. The form is not patient-specific and contains no patient information or individualized medical decision making.

139. Instead, when practitioners refer a patient to CCHS for UDT, they complete a toxicology requisition form identifying a specific patient's name and the date the sample was provided. That requisition form often directs CCHS to use the practitioner's "custom" profile. This process gives the appearance that individualized patient-specific determinations are being made.

140. In most instances, however, this process, which is directed and controlled by CCHS and Wallis, results in every UDT service offered by CCHS being "ordered" for every patient of that practitioner.

141. The physician custom profiles and the requisition forms often are filled out by CCHS employees placed by CCHS in the ordering practitioner's office or clinic.

142. For clinics with more than one practitioner, clinic management often determined what UDT services would be made part of the clinic's "custom" profile. That profile then controls for every patient treated by that clinic, regardless of which practitioner orders the testing.

143. In that situation, every patient of the clinic will receive the same level of definitive UDT unless the ordering practitioner affirmatively annotates the record to indicate they want something different. This resulted in Federal Agency GHBP beneficiary populations across multiple clinic locations and numerous practitioners all being billed for the highest and most expensive level of UDT covered by Federal Agency GHBP, regardless of the medical needs and condition of each individual beneficiary. In many of these instances, CCHS billed Federal Agency GHBP for a G0483 definitive UDT.

144. This blanket ordering process was designed and implemented by CCHS and Wallis.

b. CCHS's Billing Processes

145. Prior to June 1, 2018, CCHS used a third-party billing company that was responsible for the entire process—assigning HCPCS and/or CPT codes to services, submitting claims, receiving payments and remittance advice, and providing revenue cycle management reports to CCHS.

146. In 2018, CCHS replaced its third-party billing company with a software provider ("Vendor"). The change was motivated, at least in part, by a lack of visibility and control over denied claims and revenue reports under the prior company.

147. Unlike the prior company, the Vendor only provided billing software and customer support for setting up the software. For example, the Vendor helped CCHS and Wallis set up their automated billing process and implement the billing and coding rules used by CCHS.

148. In February 2018, representatives of the Vendor met in person with CCHS officials, including Wallis, in Oklahoma City, Oklahoma to discuss CCHS's business and the software implementation process.

149. From approximately February 2018 through May 31, 2018, CCHS and the Vendor worked together to customize, implement, and trouble-shoot the new billing software.

150. In February 2018, CCHS's billing supervisor sent the Vendor a spreadsheet at Wallis's direction. The spreadsheet contained columns identifying the toxicology tests performed by CCHS by procedure name and CCHS's internal procedure/order code. In another column, CCHS assigned a billing CPT code to each test and/or a HCPCS to each bundled panel of tests. When a specific test was performed and resulted in CCHS's laboratory information system, the corresponding HCPCS and/or CPT codes assigned by CCHS and Wallis would be used in claims for payment submitted to GHBP and other health insurance providers.

151. For example, CCHS procedure code 329 was named "Urine MCT (All-in-One)." Based on the spreadsheet CCHS provided to the Vendor, all 329 services were to be billed using CPT 80307 and HCPCS G0483.

152. As another example, CCHS procedure code 320 was named "Carbamazepine, Quant, Urine." Based on the spreadsheet CCHS provided to the Vendor, all 320 services were to be billed using CPT 80339 (Antiepileptics, not otherwise specific).

153. CCHS was solely responsible for identifying the diagnostic tests it offered and assigning the appropriate HCPCS and/or CPT codes to be used in claims submitted for payment. Wallis contributed to, directed, and approved the information in the toxicology spreadsheets that CCHS provided to the Vendor.

154. CCHS made several revisions to those HCPCS and/or CPT code assignments prior to November 16, 2018. Those changes were made at Wallis's direction and/or with his approval.

155. Wallis validated and audited all data provided to the Vendor, with assistance from CCHS staff.

156. On June 1, 2018, CCHS went live on the Vendor's billing platform.

157. All of the claims for payment at issue in this case were submitted to GHBP by CCHS, at Wallis's direction, via this software platform.

c. Medicaid Backdoor to Evade Prior Authorization Requirements

158. From at least November 2018 through 2021, CCHS submitted claims for payment to OHCA using TDM procedure codes, which are only to be used for testing whole blood, serum, plasma, or cerebrospinal fluid. The services underlying these claims for payment actually were ordinary UDT. CCHS, at Wallis's direction, misrepresented these services to evade OHCA's prior authorization requirement and obtain payment for services that were not reimbursable.

159. CCHS and Wallis knew OHCA required billing providers to obtain prior authorization before billing definitive UDT services.

160. In an email dated May 31, 2016, one of CCHS's members wrote "I'm hoping the PAR [prior authorization] requirements are more focused on pain clinics but the way it's written it may affect what we are trying to do with monitoring" for mental health and behavioral health clinics. The subject line of the preceding emails reads "Toxicology Prior Authorization for Definitive Testing" and the forwarded messages reference "that OHCA is now requiring prior authorization for Toxicology."

161. At a meeting with the Vendor in February 2018, Wallis acknowledged the Oklahoma Medicaid prior authorization requirement. The group, including Wallis, also discussed that CCHS's previous billing company did not obtain prior authorizations from OHCA. Instead, the previous billing company used individual codes other than the bundled G Codes to bill OHCA for definitive UDT.

162. In the initial procedure code spreadsheet completed by CCHS and sent to

the Vendor in February of 2018, CCHS employees working at Wallis's direction correctly coded its UDT services for all health benefit providers, including Oklahoma Medicaid.

163. More specifically, CCHS initially assigned code 80307 to its presumptive UDT and the G Codes to its bundled definitive UDT test panels.

164. When CCHS went live on the new billing platform in June 2018, CCHS did not receive the reimbursements it expected from Oklahoma Medicaid.

165. Oklahoma Medicaid denied payment on the claims submitted for payment using the G Codes because CCHS did not have prior authorization for those claims.

166. At Wallis's direction, CCHS's billing supervisor overrode the definitive UDT coding rules for Oklahoma Medicaid by adding two new codes to the claims: 82542 (Column chromatography/mass spectrometry (*e.g.*, GC/MS, or HPLC/MS), analyte not elsewhere specified) and 83789 (Mass spectrometry and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified).

167. In or around July 2018, CCHS began billing multiple units of CPT codes 82542 and 83789 for each definitive UDT service performed on a urine sample from an Oklahoma Medicaid beneficiary.

168. This change applied only to Oklahoma Medicaid beneficiaries, despite the fact that Oklahoma Medicaid required billing providers to use the G Codes. Definitive UDT for Federal Agency GHBP beneficiaries, where no prior authorization requirement existed, continued to be billed using the G Codes.

169. In an email dated August 2, 2018, CCHS's billing supervisor wrote the following to the Vendor:

> We are getting paid on some of the G codes that we changed into the 82542 and 83789. I noticed with the codes we are using we are getting paid 111.62 and [under the prior billing company] it was 161. The only difference is they didn't use the 80307 because in your CCI edits 80307 C1 bumps up against 82542 and 83789 if there is no modifier. So I was wondering if we could add the additional codes 80156, 80157, 80164, 80173, 80175, 80201 to the bill out of on going [sic] MCT claims. Let me know what you think.

170. Wallis directed the billing supervisor to request this change.

171. CPT codes 80156, 80157, 80164, 80173, 80175, 80201 are TDM codes that may only be billed for testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

172. On August 2, 2018, a representative of the Vendor responded via email as follows:

> I would recommend that you pull some of the [requisitions] that were submitted for the claims you got paid the $161.00 and see what exactly got resulted. I am very interested in seeing what actually got ran versus what they billed out.
>
> It might be a good idea to also call the payor, like we have previously discussed and see what they want.
>
> After you have done that, and you still want to proceed down the below route that is your call.

173. On September 5, 2018, the Vendor again warned CCHS, via the billing supervisor, as follows:

> In the end it comes down to what test was preformed [sic] not just what you want to bill out because you get paid more
>
> We need someone like Eric to look at what test is being performed and then

> compare them back to the CPT codes
>
> We told her that just picking and choosing random codes to bill out per test because they get paid more is illegal and if they get audited they have to be able to prove [sic]
>
> [The billing supervisor] said she will talk to [Wallis] again as he said they are inclusive to the methodology they are doing[.]

174. Neither CCHS nor Wallis ever provided the Vendor with documentation or verbal confirmation that Oklahoma Medicaid approved of CCHS's approach to billing definitive UDT.

175. At an in-person meeting between CCHS and representatives of the Vendor in Oklahoma City, Oklahoma, on November 7-8, 2018, Wallis acknowledged that Oklahoma Medicaid was not paying claims submitted for payment using the G Codes. Wallis conceded that CCHS could not meet the requirements for obtaining prior authorization from OHCA to bill its definitive UDT.

176. Wallis claimed the requested coding changes were appropriate based on the "processes" performed by the LC-MS during definitive UDT. He also claimed CCHS tests for other substances that justify adding the 5 or 6 extra codes to the Oklahoma Medicaid claims.

177. To get around the G Code denials, Wallis created a "billing only" panel called 624 within CCHS's laboratory information system. Wallis directed a CCHS lab technician to add the panel coding to all definitive UDT testing to "help" with the "billing process."

178. Panel 624 was "no billed" for all payors except Oklahoma Medicaid and

the Oklahoma Department of Mental Health Services, meaning definitive UDT billed to other payors continued to use the G Codes.

179. For Oklahoma Medicaid, Wallis's panel 624 caused the following codes to be included in the corresponding claim for payment submitted to OHCA: 80156, 80157, 80164, 80173, 80175, 80184, 82542, and 83789 (hereinafter the "Backdoor Codes").

180. On November 8, 2018, the Vendor sent Wallis and CCHS's billing supervisor a sample of what the resulting Oklahoma Medicaid claims would look like.

181. In an email dated November 9, 2018, Wallis approved removing the previously assigned procedure codes and replacing them with the Backdoor Codes.

182. CCHS submitted and Wallis caused the submission of claims that used the Backdoor Codes and were paid by OHCA beginning on November 16, 2018, and continuing through October 2019.

183. CCHS submitted and Wallis caused the submission of claims for payment using the Backdoor Codes, which misrepresented the services performed and/or represented services that were not rendered.

184. The following examples are representative of Defendants' fraudulent scheme:

a. ***Beneficiary B.C.***

i. B.C. was an Oklahoma Medicaid beneficiary referred to CCHS for UDT by Practitioner 1 via a written order dated November 29, 2018.

ii. Practitioner 1's November 29, 2018 order for UDT for B.C. stated: "Urine MCT (All-in-One)".

iii. CCHS performed UDT on the November 29, 2018 urine sample provided by B.C. The presumptive and definitive UDT test results were first available in the same report on December 4, 2018.

iv. CCHS did not have or obtain prior authorization from OHCA to bill for definitive UDT performed for B.C.

v. CCHS's patient record for B.C. does not contain any results for TDM testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

vi. On or about December 10, 2018, CCHS submitted claim number 2018345467161 for payment to OHCA requesting reimbursement for services using CPT 80156, 80157, 80164, 80173, 80175, 80184, 80201, 82542, and 83789. CCHS was the billing and rendering provider on the claim.

vii. On or about December 10, 2018, OHCA paid CCHS for the 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services in the amount of $138.57. If OHCA had known the billed 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services were not rendered, it would not have reimbursed CCHS for this billed service.

viii. If CCHS had billed for definitive UDT using the G-codes as required, OHCA would not have paid the claim because CCHS did not comply with OHCA's prior authorization requirement.

ix. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $138.57 from OHCA to which it was not entitled.

b. ***Beneficiary S.H.***

i. S.H. was an Oklahoma Medicaid beneficiary referred to CCHS for UDT by Practitioner 2 via a written order dated February 15, 2019.

ii. Practitioner 2's February 15, 2019 order for UDT for S.H. stated: "Confirmation (Expanded), Quant, Urine" and "Urine Drug Screen, Non-Quant, Urine."

iii. CCHS performed UDT on the February 15, 2019 urine sample provided by S.H. The presumptive and definitive UDT test results were first available in the same report on February 19, 2019.

iv. CCHS did not have or obtain prior authorization from OHCA to bill for definitive UDT performed for S.H.

v. CCHS's patient record for S.H. does not contain any results for TDM testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

vi. On or about February 25, 2019, CCHS submitted claim number 2019057403193 for payment to OHCA requesting reimbursement for services using CPT 80156, 80157, 80164, 80173, 80175, 80184, 80201, 82542, and 83789. CCHS was the billing and rendering provider on the claim.

vii. On or about February 25, 2019, OHCA paid CCHS for the 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services in the amount of $130.13. If OHCA had known the billed 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services were not rendered, it would not have reimbursed CCHS for this billed service.

viii. If CCHS had billed for definitive UDT using the G-codes as required, OHCA would not have paid the claim because CCHS did not comply with OHCA's prior authorization requirement.

ix. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $130.13 from OHCA to which it was not entitled.

c. ***Beneficiary C.L.***

i. C.L. was an Oklahoma Medicaid beneficiary referred to CCHS for UDT by Practitioner 3 via a written order dated March 15, 2019.

ii. Practitioner 3's March 15, 2019 order for UDT for C.L. stated: "I hereby authorize Coordinated Care Health Solutions (CCHS) to perform the urine drug test panel as indicated on this form."

iii. CCHS performed UDT on the March 15, 2019 urine sample provided by C.L. The presumptive and definitive UDT test results were first available in the same report on March 20, 2019.

iv. CCHS did not have or obtain prior authorization from OHCA to bill for definitive UDT performed for C.L.

v. CCHS's patient record for C.L. does not contain any results for TDM testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

vi. On or about March 25, 2019, CCHS submitted claim number 2019084407136 for payment to OHCA requesting reimbursement for services using CPT 80156, 80157, 80164, 80173, 80175, 80184, 80201, 82542, and 83789. CCHS was the billing and rendering provider on the claim.

vii. On or about March 25, 2019, OHCA paid CCHS for the 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services in the amount of $130.13. If OHCA had known the billed 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services

were not rendered, it would not have reimbursed CCHS for this billed service.

viii. If CCHS had billed for definitive UDT using the G-codes as required, OHCA would not have paid the claim because CCHS did not comply with OHCA's prior authorization requirement.

ix. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $130.13 from OHCA to which it was not entitled.

d. ***Beneficiary T.M.***

i. T.M. was an Oklahoma Medicaid beneficiary referred to CCHS for UDT by Practitioner 4 via a written order dated April 10, 2019.

ii. Practitioner 4's April 10, 2019 order for UDT for T.M. stated: "I hereby authorize Coordinated Care Health Solutions (CCHS) to perform the urine drug test panel as indicated on this form."

iii. CCHS performed UDT on the April 10, 2019 urine sample provided by T.M. The presumptive and definitive UDT test results were first available in the same report on April 15, 2019.

iv. CCHS did not have or obtain prior authorization from OHCA to bill for definitive UDT performed for T.M.

v. CCHS's patient record for T.M. does not contain any results for TDM testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

vi. On or about April 19, 2024, CCHS submitted claim number 2019109423948 for payment to OHCA requesting reimbursement for services using CPT 80156, 80157, 80164, 80173, 80175, 80184, 80201, 82542, and 83789. CCHS was the billing and rendering provider on the claim.

vii. On or about April 19, 2024, OHCA paid CCHS for the 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services in the amount of $130.13. If OHCA had known the billed 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services were not rendered, it would not have reimbursed CCHS for this billed service.

viii. If CCHS had billed for definitive UDT using the G-codes as required, OHCA would not have paid the claim because CCHS did not comply with OHCA's prior authorization requirement.

ix. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $130.13 from OHCA to which it was not entitled.

e. ***Beneficiary J.N.***

i. J.N. was an Oklahoma Medicaid beneficiary referred to CCHS for UDT by Practitioner 3 via a written order dated March 25, 2019.

ii. Practitioner 3's March 25, 2019 order for UDT for J.N. stated: "I hereby authorize Coordinated Care Health Solutions (CCHS) to perform the urine drug test panel as indicated on this form."

iii. CCHS performed UDT on the March 25, 2019 urine sample provided by J.N. The presumptive and definitive UDT test results were first available in the same report at on March 28, 2019.

iv. CCHS did not have or obtain prior authorization from OHCA to bill for definitive UDT performed for J.N.

v. CCHS's patient record for J.N. does not contain any results for TDM testing performed on whole blood, serum, plasma, or cerebrospinal fluid.

vi. On or about April 8, 2019, CCHS submitted claim number 2019098457218 for payment to OHCA requesting reimbursement for services using CPT 80156, 80157, 80164, 80173, 80175, 80184, 80201, 82542, and 83789. CCHS was the billing and rendering provider on the claim.

vii. On or about April 8, 2019, OHCA paid CCHS for the 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services in the

amount of $130.13. If OHCA had known the billed 80156, 80157, 80164, 80173, 80175, 80184, 80201, and 82542 services were not rendered, it would not have reimbursed CCHS for this billed service.

viii. If CCHS had billed for definitive UDT using the G-codes as required, OHCA would not have paid the claim because CCHS did not comply with OHCA's prior authorization requirement.

ix. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $130.13 from OHCA to which it was not entitled.

185. By letter dated October 10, 2019, Medicaid payments to CCHS were suspended based on a credible allegation of fraud. That payment suspension is still in effect.

186. On September 30, 2021, CCHS's provider contract with OHCA expired.

d. Defendants Billed for Presumptive UDT That Was Not Rendered

187. From at least November 2018 through December 31, 2022, CCHS routinely billed the Federal Agency GHBP for a corresponding presumptive UDT service for each billed definitive UDT service. The two services were for the same Federal Agency GHBP beneficiary on the same date of service.

188. From November 2018 through 2022, approximately 98% of the paid presumptive UDT claims billed to Medicare by CCHS included definitive HCPCS codes on the same date of service for the same beneficiary.

189. When the presumptive and definitive tests were performed on different machines, CCHS, under Wallis's direction, designed its workflow such that the presumptive UDT results could not be viewed outside CCHS's laboratory information system until the definitive UDT was completed.

190. After CCHS moved its presumptive UDT to the LC-MS machine, only one test was performed. To make it appear that two distinct services were rendered, the test results were split into a "presumptive result" section and a "definitive result" section.

191. For all claims at issue in this case, the presumptive and definitive UDT results were made available to the ordering practitioner at the same time and in the same document.

192. Because definitive UDT allegedly was also ordered in these instances, CCHS and Wallis knew there was no medical reason to result, let alone bill, an LC-MS presumptive test.

193. The ordering practitioners did not have or use these "presumptive test results" to inform and determine what, if any, definitive testing was necessary. The ordering practitioners also did not use these "presumptive test results" for the diagnosis or treatment of illness or injury, nor were those results used in the management of beneficiaries' specific medical problems.

194. CCHS submitted and Wallis caused the submission of claims for payment to Federal Agency GHBP for presumptive UDT services that were not rendered or reimbursable.

195. The following examples are representative of Defendants' fraudulent schemes:

a. ***Beneficiary B.M.***

i. B.M. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 4 via a written order dated November 14, 2018.

ii. Practitioner 4's November 14, 2018 order for UDT for B.M. stated: "USE Custom Panel." The presumptive drug screen options on the November 14, 2018 were not selected.

iii. CCHS performed definitive UDT on the November 14, 2018 urine sample provided by B.M. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report at on November 17, 2018.

iv. On or about November 26, 2018, CCHS submitted claim number 911118330016550 for payment to one Federal Agency GHBP requesting reimbursement for services using codes 80307 and G0483. CCHS was the billing and rendering provider on the claim.

v. On or about December 10, 2018, the Federal Agency GHBP paid CCHS for the 80307 service in the amount of $70.39. If the Federal Agency GHBP had known the billed 80307 presumptive urine drug test was not rendered, not medically necessary, or not used in the

treatment of the beneficiary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $70.39 from the Federal Agency GHBP to which it was not entitled.

b. ***Beneficiary A.D.***

i. A.D. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 5 via a written order dated December 4, 2019.

ii. Practitioner 5's December 4, 2019 order for A.D. for UDT stated: "Presumptive drug screen to be performed by CCHS" and "USE Custom Panel."

iii. CCHS performed definitive UDT on the December 4, 2019 urine sample provided by A.D. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on December 7, 2019.

iv. On or about December 12, 2019, CCHS submitted claim number 911119346019110 for payment to one Federal Agency GHBP requesting reimbursement for services using codes 80307 and G0483. CCHS was the billing and rendering provider on the claim.

v. On or about December 26, 2019, the Federal Agency GHBP paid CCHS for the 80307 service in the amount of $63.36. If the Federal

Agency GHBP had known the billed 80307 presumptive urine drug test was not rendered, not medically necessary, or not used in the treatment of the beneficiary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $63.36 from the Federal Agency GHBP to which it was not entitled.

c. ***Beneficiary C.M.***

i. C.M. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 6 via a written order dated January 15, 2020.

ii. Practitioner 6's January 15, 2020 order for C.M. for UDT selected every drug class under the "Other Test(s) Required." The presumptive drug screen options on the January 15, 2020 were not selected.

iii. CCHS performed definitive UDT on the January 15, 2020 urine sample provided by C.M. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on January 21, 2020.

iv. On or about January 27, 2020, CCHS submitted claim number 911120027363400 for payment to one Federal Agency GHBP

requesting reimbursement for services using codes 80307 and G0483. CCHS was the billing and rendering provider on the claim.

v. On or about February 10, 2020, the Federal Agency GHBP paid CCHS for the 80307 service in the amount of $60.90. If the Federal Agency GHBP had known the billed 80307 presumptive urine drug test was not rendered, not medically necessary, or not used in the treatment of the beneficiary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $60.90 from the Federal Agency GHBP to which it was not entitled.

d. ***Beneficiary C.B.***

i. C.B. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 1 via a written order dated March 19, 2021.

ii. Practitioner 1's March 19, 2021, order for C.B. for UDT stated: "329 Urine MCT (All-in-One)."

iii. CCHS performed definitive UDT on the March 19, 2021 urine sample provided by C.B. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on March 29, 2021.

iv. On or about April 5, 2021, CCHS submitted claim number 911121095382410 for payment to one Federal Agency GHBP requesting reimbursement for services using codes 80307 and G0483. CCHS was the billing and rendering provider on the claim.

v. On or about April 19, 2021, the Federal Agency GHBP paid CCHS for the 80307 service in the amount of $62.14. If the Federal Agency GHBP had known the billed 80307 presumptive urine drug test was not rendered, not medically necessary, or not used in the treatment of the beneficiary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $62.14 from the Federal Agency GHBP to which it was not entitled.

e. ***Beneficiary B.M.***

i. B.M. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 7 via a written order dated October 3, 2022.

ii. Practitioner 7's October 3, 2022, order for UDT for B.M. stated: "Presumptive drug screen to be performed by CCHS" and selected five drug classes for definitive testing.

iii. CCHS performed definitive UDT on the October 3, 2022 urine sample provided by B.M. The test results were split into a

"presumptive result" section and a definitive result section, both of which were first available in the same report on October 6, 2022.

iv. On or about November 10, 2022, CCHS submitted claim number 911122314052430 for payment to one Federal Agency GHBP requesting reimbursement for services using codes 80307 and G0482. CCHS was the billing and rendering provider on the claim.

v. On or about November 25, 2022, the Federal Agency GHBP paid CCHS for the 80307 service in the amount of $60.90. If the Federal Agency GHBP had known the billed 80307 presumptive urine drug test was not rendered, not medically necessary, or not used in the treatment of the beneficiary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $60.90 from the Federal Agency GHBP to which it was not entitled.

e. Defendants Blanket Billed for Non-reimbursable Definitive UDT and/or Definitive UDT That Was Not Ordered

196. From at least November 2018 through January 2023, CCHS routinely billed Federal Agency GHBP for definitive UDT services using HCPCS code G0483 irrespective of whether or not such services were ordered and/or medically reasonable and necessary. On information and belief, this conduct was ongoing through at least December 31, 2023.

197. CCHS billed Federal Agency GHBP for these definitive UDT services at Wallis's direction.

198. On average, more than 65% of the definitive UDT claims submitted for payment by CCHS to Medicare used HCPCS code G0483. HCPCS G0483 corresponds to the most expansive and expensive definitive UDT covered by Federal Agency GHPB.

199. These definitive UDT services were not ordered, performed, or billed as a result of individualized patient assessments of clinical history and risk.

200. In most instances, the written order from the practitioner was not a patient-specific determination nor did it limit the drug classes to be tested to those that were medically and reasonably necessary for the treatment of the beneficiary. Instead, CCHS established the Physician Custom Profile process to conceal blanket orders.

201. Indeed, when CCHS signed a new clinic on as a customer, Wallis directed CCHS employees to make sure the clinic filled out the Physician Custom Profile form.

202. In or around November 2019, Practitioners 8 and 9 learned that CCHS was performing definitive UDT on samples provided by patients of the practitioners' pain management clinic ("Clinic 1") that the practitioners did not order. Practitioners 8 and 9 contacted a marketing representative of CCHS about the unauthorized definitive UDT.

203. In or around November 2019, Practitioners 8 and 9 met the CCHS marketing representative in person and instructed CCHS to stop performing the unauthorized definitive UDT.

204. On or about December 17, 2019, the practitioners again advised the

CCHS marketing representative that unauthorized tests were being performed by CCHS. Practitioner 8 wrote:

> we met November 1st and shouldn't still have had issues after our discussion that day. We had every patient get a confirmation for opiates when we did not request it [sic] I checked 11/19 and 11/20. … Please make sure this is corrected and clear to your lab.

205. Despite multiple communications from the ordering practitioners that definitive UDT was neither ordered, authorized, nor medically necessary, CCHS continued to fraudulently bill GHBP for definitive UDT services for Clinic 1's patients using codes G0481 and G0483.

206. To conceal the ongoing fraud, in or around November 2019, CCHS either stopped reporting definitive UDT results and/or stopped sending definitive UDT results to Practitioners 8 and 9 but continued to bill Federal Agency GHBP for such services.

207. CCHS's patient files corresponding to certain claims for payment submitted by CCHS and caused to be submitted by Wallis for definitive UDT allegedly ordered by Practitioners 8 and 9 do not contain any definitive UDT results.

208. Unlike Oklahoma Medicaid, the Federal Agency GHBP did not require prior authorization to bill the G Codes. CCHS and Wallis knew they could not meet the prior authorization medical necessity requirements to bill Medicaid for G0483 definitive UDT services. But, because no prior authorization requirements existed for Federal Agency GHBP, CCHS, under Wallis's direction, knowingly billed these medically unnecessary and non-reimbursable services to Federal Agency GHBP.

209. In doing so, Defendants knew, recklessly disregarded or were

deliberately ignorant of the requirements for billing UDT to Federal Agency GHBP.

210. CCHS submitted and Wallis caused to be submitted claims for payment to Federal Agency GHBP for definitive UDT services that they knew were not rendered, not medically necessary, not used in the treatment of Federal Agency GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the practitioners.

211. As a result of Defendants' conduct, Federal Agency GHBP paid millions of dollars for thousands of false and/or fraudulent claims for non-covered definitive UDT services.

212. Medicare was particularly susceptible to Defendants' fraudulent schemes because it generally does not require a patient co-payment on laboratory services.

213. The following examples are representative of Defendants' fraudulent schemes:

a. ***Beneficiary S.S.***

i. S.S. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 10 via a written order dated November 7, 2018.

ii. Practitioner 10's November 7, 2018, order for UDT for S.S. stated: "329 Urine MCT (All-in-One)."

iii. CCHS performed definitive UDT on the November 7, 2018 urine sample provided by S.S. The test results were split into a

"presumptive result" section and a definitive result section, both of which were first available in the same report on November 13, 2018.

iv. On or about November 19, 2018, CCHS submitted claim number 911118323316290 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about December 3, 2018, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $241.98. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $241.98 from the Federal Agency GHBP to which it was not entitled.

b. ***Beneficiary M.F.***

i. M.F. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 4 via a written order dated April 29, 2019.

ii. Practitioner 4's April 29, 2019, order for UDT for M.F. stated: "USE Custom Panel."

iii. CCHS performed definitive UDT on the April 29, 2019 urine sample provided by M.F. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on May 3, 2019.

iv. On or about May 8, 2019, CCHS submitted claim number 911119128015350 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about May 22, 2019, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $241.98. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $241.98 from the Federal Agency GHBP to which it was not entitled.

c. ***Beneficiary S.D.***

i. S.D. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 9 via a written order dated October 7, 2019.

ii. Practitioner 9's October 7, 2019 order for S.D. for UDT stated: "Presumptive Drug Screen to be Performed by CCHS." No definitive tests were ordered.

iii. Even though definitive UDT was not ordered by Practitioner 9, CCHS performed definitive UDT on the October 7, 2019 urine sample provided by S.D. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on October 11, 2019.

iv. On or about October 15, 2019, CCHS submitted claim number 911119288595350 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about October 29, 2019, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $241.98. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $241.98 from the Federal Agency GHBP to which it was not entitled.

d. ***Beneficiary S.D.***

i. S.D. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 9 via a written order dated December 5, 2019.

ii. Practitioner 9's December 5, 2019 order for S.D. for UDT stated: "Presumptive Drug Screen to be Performed by CCHS." No definitive tests were ordered.

iii. CCHS performed UDT on the December 5, 2019 urine sample provided by S.D. Presumptive UDT results were reported and made available to the ordering practitioner on December 10, 2019. There are no definitive UDT results in CCHS's or Practitioner 9's patient files.

iv. Even though definitive UDT was not ordered, on or about December 16, 2019, CCHS submitted claim number 911119350310550 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0481. CCHS was the billing and rendering provider on the claim.

v. On or about December 30, 2019, the Federal Agency GHBP paid CCHS for the G0481 service in the amount of $153.46. If the Federal Agency GHBP had known the billed G0481 definitive urine drug test was not rendered, billed pursuant to impermissible blanket

orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $153.46 from the Federal Agency GHBP to which it was not entitled.

e. ***Beneficiary J.A.***

i. J.A. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 8 via a written order dated December 31, 2019.

ii. Practitioner 8's December 31, 2019 order for J.A. for UDT stated: "Presumptive Drug Screen to be Performed by CCHS." No definitive tests were ordered.

iii. CCHS performed UDT on the December 31, 2019 urine sample provided by J.A. Presumptive UDT results were reported and made available to the ordering practitioner on January 4, 2020. There are no definitive UDT results in CCHS's or Practitioner 8's patient files.

iv. Even though definitive UDT was not ordered, on or about January 9, 2020, CCHS submitted claim number 911120009025600 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0481. CCHS was the billing and rendering provider on the claim.

v. On or about January 23, 2020, the Federal Agency GHBP paid CCHS for the G0481 service in the amount of $153.46. If the Federal Agency GHBP had known the billed G0481 definitive urine drug test was not rendered, billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $153.46 from the Federal Agency GHBP to which it was not entitled.

f. ***Beneficiary J.C.***

i. J.C. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 5 via a written order dated June 2, 2020.

ii. Practitioner 5's June 2, 2020 order for J.C. for UDT stated: "USE Custom Panel."

iii. CCHS performed definitive UDT on the June 2, 2020 urine sample provided by J.C. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on June 5, 2020.

iv. On or about June 10, 2020, CCHS submitted claim number 911120162044610 for payment to one Federal Agency GHBP

requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about June 24, 2020, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $246.92. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $246.92 from the Federal Agency GHBP to which it was not entitled.

g. ***Beneficiary C.B.***

i. C.B. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 1 via a written order dated March 19, 2021.

ii. Practitioner 1's March 19, 2021, order for UDT for C.B. stated: "329 Urine MCT (All-in-One)."

iii. CCHS performed definitive UDT on the March 19, 2021 urine sample provided by C.B. The test results were split into a "presumptive result" section and a definitive result section, both of which were first available in the same report on March 29, 2021.

iv. On or about April 5, 2021, CCHS submitted claim number 911121095382410 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about April 9, 2021, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $246.92. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $246.92 from the Federal Agency GHBP to which it was not entitled.

h. ***Beneficiary C.B.***

i. C.B. was a Federal Agency GHBP beneficiary referred to CCHS for UDT by Practitioner 1 via a written order dated January 5, 2023.

ii. Practitioner 1's January 5, 2023, order for C.B. for UDT stated: "329 Urine MCT (All-in-One)."

iii. CCHS performed definitive UDT on the January 5, 2023 urine sample provided by C.B. The test results were split into a

"presumptive result" section and a definitive result section, both of which were first available in the same report on January 9, 2023.

iv. On or about January 17, 2023, CCHS submitted claim number 911823017037720 for payment to one Federal Agency GHBP requesting reimbursement for definitive UDT services using code G0483. CCHS was the billing and rendering provider on the claim.

v. On or about January 31, 2023, the Federal Agency GHBP paid CCHS for the G0483 service in the amount of $241.98. If the Federal Agency GHBP had known the billed G0483 definitive urine drug test was billed pursuant to impermissible blanket orders, not ordered by a practitioner, or not medically necessary, it would not have reimbursed CCHS for this billed service.

vi. As a result of Defendants' fraudulent conduct, and the submission of the false or fraudulent claims, CCHS received $241.98 from the Federal Agency GHBP to which it was not entitled.

214. Because CCHS knowingly submitted and Wallis knowingly caused the submission of GHBP UDT claims that misrepresented the services performed, included services not rendered, included medically unnecessary services and/or unauthorized services, and did not comply with program requirements, the claims were false or fraudulent and not payable. Accordingly, the United States and State of Oklahoma seek to recover damages, along with appropriate trebling of those damages, and penalties for each false claim submitted or caused to be submitted by Defendants.

FIRST CLAIM FOR RELIEF

Violations of the FCA: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

215. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

216. The United States seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA.

217. Defendants knowingly presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims for reimbursement by GHBP, for services that were misrepresented, not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the practitioner. These claims were both factually and legally false or fraudulent.

218. GHBP would not have paid these false and fraudulent claims had they known that the services were misrepresented, not rendered, not medically necessary, not

used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the practitioner.

219. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

220. The United States, unaware of the falsity of the claims submitted for payment or caused to be submitted for payment by Defendants, approved, paid, and participated in payments made by GHBP for false or fraudulent claims that would otherwise not have been approved and paid.

221. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CLAIM FOR RELIEF

Violations of the FCA: Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

222. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

223. The United States seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA.

224. As detailed above, Defendants knowingly made, used, or caused to be made or used, false records or statements, which included the false statements, express and implied certifications and representations on claim forms, the EDI, and multiple

Medicare 855B forms, to obtain approval for and payment by the United States for false or fraudulent claims as detailed above.

225. The false statements, express and implied certifications, and representations made, used, or caused to be made or used by Defendants were material to the payment of the false claims by the United States.

226. The false statements, express and implied certifications, and representations were made, used, or caused to be made or used with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

227. The United States, unaware of the falsity of the records and statements made, used, or caused to be made or used by Defendants, approved, paid, and participated in payments made by GHBP for false or fraudulent claims that would otherwise not have been approved and paid.

228. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

THIRD CLAIM FOR RELIEF

Violations of the Oklahoma Medicaid False Claims Act:
Presenting False Claims for Payment
(63 Okla. Stat. § 5053.1(B)(1))

229. The State of Oklahoma realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

230. The State of Oklahoma seeks relief against Defendants under Section 5053.1(B)(1) of the OFCA.

231. Defendants knowingly presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the State of Oklahoma, including claims for reimbursement by OHCA, by misrepresenting the services allegedly performed and billing for services not rendered. These claims were both factually and legally false or fraudulent.

232. OHCA would not have paid these false and fraudulent claims had they known that the services had been misrepresented and were not rendered.

233. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

234. The State of Oklahoma, unaware of the falsity of the claims submitted for payment or caused to be submitted for payment by Defendants, approved, paid, and participated in payments made by OHCA for false or fraudulent claims that would otherwise not have been approved and paid.

235. By reason of the false or fraudulent claims, the State of Oklahoma has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

FOURTH CLAIM FOR RELIEF

Violations of the Oklahoma Medicaid False Claims Act:
Use of False Statements
(63 Okla. Stat. § 5053.1(B)(2))

236. The State of Oklahoma realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

237. The State of Oklahoma seeks relief against Defendants under Section 5053.1(B)(2) of the OFCA.

238. As detailed above, Defendants knowingly made, used, or caused to be made or used, false records or statements, which included the false statements, express and implied certifications, and representations on claim forms to obtain approval for and payment by the State of Oklahoma for false or fraudulent claims as detailed above.

239. The false statements, express and implied certifications, and representations made, used, or caused to be made or used by Defendants were material to the payment of the false or fraudulent claims by the State of Oklahoma.

240. The false statements, express and implied certifications, and representations were made, used, or caused to be made or used with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

241. The State of Oklahoma, unaware of the falsity of the records and statements made, used, or caused to be made or used by Defendants, approved, paid, and participated in payments made by OHCA for false or fraudulent claims that would otherwise not have been approved and paid.

242. By reason of these false records or statements, the State of Oklahoma has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

FIFTH CLAIM FOR RELIEF (DEFENDANT CCHS ONLY)

Payment by Mistake
(Federal Common Law)

243. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

244. The United States paid CCHS, either directly or indirectly, for claims submitted or caused to be submitted by CCHS for services that were misrepresented, not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the practitioner, without knowledge of material facts, and under the mistaken belief that CCHS was entitled to receive payment for such claims.

245. The mistaken belief of the United States was material to its decision to pay CCHS on such claims.

246. CCHS intended that the United States would rely on their false statements, representations, and material omissions of fact.

247. The United States reasonably relied on CCHS's false statements, representations, and material omissions of fact and, as a result, paid CCHS money that it otherwise would not have been paid.

248. The United States has been damaged as a result of these mistaken payments and is entitled to recover the amount of the payments in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF (DEFENDANT CCHS ONLY)

Unjust Enrichment
(Federal Common Law)

249. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

250. The United States paid claims submitted to GHBP in connection with CCHS's UDT services based on false claims and statements submitted to GHBP.

251. By retaining monies and profits received from services that were not reimbursable, CCHS retained money that was the property of GHBP to which it was not entitled.

252. The United States seeks the recovery of all funds paid by GHBP by which CCHS has been unjustly enriched, including profits unlawfully received from UDT services at CCHS's lab and other amounts paid based on claims for services that were misrepresented, not rendered, not medically necessary, not used in the treatment of GHBP beneficiaries, billed pursuant to impermissible blanket orders, and/or not ordered by the practitioner.

253. As a consequence of the acts set forth above, CCHS was unjustly enriched at the expense of the United States in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States.

SEVENTH CLAIM FOR RELIEF

Fraud
(Federal Common Law)

254. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

255. Defendants made materially false statements and representations, including material omissions of fact, to the United States to obtain money from GHBP to which they were not entitled.

256. Defendants made such statements and representations with knowledge of their materiality and falsity.

257. Defendants also failed to tell GHBP about the fraudulent activity at CCHS, which was a material omission.

258. Defendants made such materially false statements, representations, and omissions with the intent that the United States would rely on them in making determinations to pay claims submitted to GHBP.

259. The United States reasonably relied on Defendants' material misrepresentations and omissions.

260. The United States was injured as a result of Defendants' unlawful conduct in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF (DEFENDANT CCHS ONLY)

Payment by Mistake
(Oklahoma Common Law)

261. The State of Oklahoma realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

262. The State of Oklahoma paid CCHS, either directly or indirectly, for claims submitted by CCHS for services that were misrepresented and not rendered, without knowledge of material facts, and under the mistaken belief that CCHS was entitled to receive payment for such claims.

263. The mistaken belief of the State of Oklahoma was material to its decision to pay CCHS on such claims.

264. CCHS intended that the State of Oklahoma would rely on its false statements, representations, and material omissions of fact.

265. The State of Oklahoma reasonably relied on CCHS's false statements, representations, and material omissions of fact and, as a result, paid CCHS money that it otherwise would not have been paid.

266. The State of Oklahoma has been damaged as a result of these mistaken payments and is entitled to recover the amount of the payments in an amount to be determined at trial.

NINTH CLAIM FOR RELIEF (DEFENDANT CCHS ONLY)

Unjust Enrichment
(Oklahoma Common Law)

267. The State of Oklahoma realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

268. The State of Oklahoma paid claims submitted to Medicaid in connection with CCHS's UDT services based on false claims and statements submitted to the State of Oklahoma.

269. By retaining monies and profits received from services that were not reimbursable, CCHS retained money that was the property of the State of Oklahoma to which it was not entitled.

270. The State of Oklahoma seeks the recovery of all funds paid by the State of Oklahoma by which CCHS has been unjustly enriched at the expense of the State of Oklahoma, including profits unlawfully received from UDT services at CCHS's lab and other amounts paid based on claims for services that were misrepresented and not rendered.

271. As a consequence of the acts set forth above, CCHS was unjustly enriched at the expense of the State of Oklahoma in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the State of Oklahoma.

TENTH CLAIM FOR RELIEF

Fraud
(Oklahoma Common Law)

272. The State of Oklahoma realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

273. Defendants made materially false statements and representations, including material omissions of fact, to the State of Oklahoma to obtain money from the State of Oklahoma to which they were not entitled.

274. Defendants made such statements and representations with knowledge of their materiality and falsity.

275. Defendants also failed to tell the State of Oklahoma about the fraudulent activity at CCHS, which was a material omission.

276. Defendants made such materially false statements, representations, and omissions with the intent that the State of Oklahoma would rely on them in making determinations to pay claims submitted to the State of Oklahoma.

277. The State of Oklahoma reasonably relied on Defendants' material misrepresentations and omissions.

278. The State of Oklahoma was injured as a result of Defendants' unlawful conduct in an amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, the United States respectfully requests judgment be entered in its favor and as follows:

a. Against Defendants jointly and severally on Claims for Relief One and Two (FCA), treble damages and civil penalties in the maximum amount allowed by law;

b. Against Defendant CCHS on Claims for Relief Five (Payment by Mistake) and Six (Unjust Enrichment), damages to the extent allowed by law;

c. Against Defendants jointly and severally on Claim for Relief Seven (Fraud), damages to the extent allowed by law;

d. All costs associated with prosecuting this civil action, as provided by law;

e. Interest on all amounts owed to the United States, as provided by law; and

f. For all other relief the Court deems just and proper;

and the State of Oklahoma respectfully requests judgment be entered in its favor and as follows:

a. Against Defendants jointly and severally on Claims for Relief Three and Four (OMFCA), treble damages and civil penalties in the maximum amount allowed by law;

b. Against Defendant CCHS on Claims for Relief Eight (Payment by Mistake) and Nine (Unjust Enrichment), damages to the extent allowed by law;

c. Against Defendants jointly and severally on Claim for Relief Ten (Fraud), damages to the extent allowed by law;

d. All costs associated with prosecuting this civil action, as provided by law;

e. Interest on all amounts owed to the State of Oklahoma, as provided by law; and

f. For all other relief the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States and the State of Oklahoma demand a trial by jury on all issues so triable.

Respectfully submitted,

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